

## IRIS Public Stakeholder Meeting

### Webinar Q&A

**Andrew Cutz, CIH:** Hi! I forgot my login name and password but signed in as a guest. Can you please send me any follow up information at <627788@ican@net> / <andrewcutz@hotmail.com>.

**Kacee:** Hi Andrew - Yes, we will record your name and email address for any follow up information.

**Andrew:** Kacee: Can you please let us know where we could download the presentations (PowerPoint). Thank you

**Kacee:** Andrew - The slides will be posted on the IRIS Public Meeting website after the meeting. This website can be found at: <http://www.epa.gov/iris/publicmeeting.htm>

**Andrew:** Thank you! I had bookmarked the <http://www.epa.gov/iris/publicmeeting.htm> and will wait for the announcement. What is your timeline?

**Kacee:** Hopefully within a few days. We will put an announcement on our homepage ([www.epa.gov/iris](http://www.epa.gov/iris)).

**Andrew:** Where are the overheads?

**Kacee:** Dr. Birnbaum doesn't have slides. But I think when she approached the podium, a cord may have been bumped which cut off the projector. We will fix it during the break. Thanks!

**David Szabo, FDA:** Will these slides be made available to the meeting participants? Either through email or the IRIS website?

**Kacee:** David - The slides will be posted on the IRIS Public Meeting website after the meeting. This website can be found at: <http://www.epa.gov/iris/publicmeeting.htm>

**David:** Thank you Kacee.

**David:** David Szabo from the Food and Drug Administration, new Center for Tobacco Products. Directed to Vince, Ken and/or Linda. Comment: IRIS should be applauded for their progress on improving positive stakeholder involvement (virtual clapping). Question: In keeping with systematic reviews, focusing on the evaluation of study quality, are there any guidelines/criteria used for the evaluation of study quality? If so, are the guidelines/criteria available for viewing? If there are no formal criteria/guidelines being used, are there efforts at a minimum to develop such a criteria list?

**Kacee:** David - thanks. Your questions are in the queue.

**Pamela Miller, Alaska Community Action on Toxics:** How will IRIS ensure objectivity in evaluating studies and ensure that the process removes the inherent bias of industry funded science and scientists?

**Kacee:** Hi Pamela - would you like to put this question in line for the Open Forum? If so, what is your affiliation? I will read your question once we are at the Q&A or open forum time.

**Pamela:** Yes, please. I am with the non-profit environmental health research and advocacy organization, Alaska Community Action on Toxics.

**Kacee:** Thanks. You are first in line once we start Q&A/comments.

**Kacee:** Pamela - is your question directed to a specific panelist (Vince or Ken?) or to EPA in general?

**Pamela:** Either Ken or Vince or other EPA IRIS program person.

**Kacee:** Thanks.

**Pamela:** The importance of the IRIS program for public health cannot be overstated and it is critical to have an easily trackable system for the public to evaluate progress and efficacy. EPA's primary mission is to protect health and the environment. As noted by speaker Richard Denison, if IRIS assessments are delayed as we have seen in the past, people will continue to suffer unnecessary and harmful illnesses that should be preventable. We think that it is so incredibly important to have accurate, unbiased, and timely assessments of chemical hazards in order to prevent unnecessary illnesses that include birth defects, cancers, adverse reproductive and other health outcomes that we see in our communities. This is not an abstract issue for workers and communities who experience unnecessary and harmful exposures.

**David Mellard, ATSDR:** Consider providing a plain-language explanation of BMD, BMDL and HED/HEC. I'm not asking for a grade school explanation but rather an explanation that is geared for health scientists and that doesn't rely on the relatively new jargon surrounding BMDs and HED/HECs. For example, the following statement is difficult for even some toxicologists to understand: "For Johnson et al, the HED99, BMDL01 is the 99th percentile...HED to the rate internal dose BMDL01 of 0.0142 mg TCE oxidized/kg<sup>3</sup>/4/day. Understanding the joint term 'HED99, BMDL01' is particularly difficult even for toxicologists. I've seen some toxicologists state this is a NOAEL.

**Kacee:** Thanks David. Would you like me to read this comment during the Open Forum session?

**David:** Yes.

**Kacee:** Okay. You are second line for questions/comments from the webinar. Can you please tell me your affiliation?

**David:** ATSDR.

**Kacee:** Thanks.

**David Farrer, Oregon Health Authority:** Great caution should be exercised if stakeholders are to have access/dialogue with peer reviewers. If such access were to be granted, it would be critical that safeguards were put in place to prevent an unbalanced amount of airtime given to particular stakeholder groups, especially those with financial interests in the outcomes of assessments.

**Kacee:** Hi David - Thanks for the comment. Would you like this to be read during the open forum session?

If so, please let me know what your affiliation is. Thanks!

**David:** Yes please. I am with the Oregon Health Authority. This is basically public health at the state level in Oregon.

**Kacee:** David - you are third in line for questions/comments from the webinar once we get to the open forum session. Thanks!

**David:** If peer reviewers are to dialogue with stakeholders, peer reviewers should be presented with conflict of interest information on the stakeholders along with the communication from the stakeholders, and that communication between stakeholders and peer reviewers (along with conflict of interest information for both parties) should be publicly available.

**Kacee:** Thanks David. I will add this to your previous comment.

**David:** Perfect. Thanks! If it wasn't clear, these comments apply to Dr. Fischer's (from ACC) suggestion that stakeholders have access to peer reviewers.

**Kacee:** Got it - thanks!

**David:** I second Gloria Post's comment that state representatives will be better able to participate if 1- documents are concise and clear, 2- fewer, more strategically timed points in the process to contribute comment, and 3- more availability of webinar participation like this.

**Bob Benson, EPA Region 9:** Dr. Fischer: Can you give an example of a WOE scheme that assigns and applies quantitative values to an array of toxicological studies?

**Kacee:** Thanks Bob. You are in the queue for questions/comments from the webinar once we get to the open forum time.

**Jim Ball, NCEA:** It would be nice to see the people asking the questions.

**Kathleen Curtis, Clean & Healthy New York:** The robust participation in today's webinar is due not to EPA, but despite EPA. IRIS needs a much more effective way to alert the public, who is obviously concerned about these issues, or would be if they knew more. The IRIS program is not redundant, it's essential. The chemical industry is

not the public and does not represent public concerns. It gets preferential treatment under the current system. IRIS should have a readily trackable, publicly accessible system as well as a listserv that shows where the review process is for any particular chemical, and if it is delayed what the reasons are.

**Kacee:** Hi Kathleen - I will put this comment in the list for the open forum. What is your affiliation?

**Kathleen:** Executive Director, Clean and Healthy New York.

**Kacee:** Thanks! You are about 5th in line for questions/comments from the webinar.

**Kathleen:** ok great. Are you going to take questions from those present in the room first?

**Kacee:** We are alternating between webinar and room.

**Kathleen:** Please pose the question at the end!!

**Kacee:** Sorry Kathleen! Was the question, How can IRIS actualize those recommendations?

**Kathleen:** That was the one.

**Kacee:** Kathleen - one more question. When you say "those recommendations" are you talking about alerting the public or a tracking system for IRIS. Or both?

**Kathleen:** Never mind Kacee, it's cool. I consider the tracking system and the alerts and invitations to all be linked portions of public engagement, transparency and inclusion.

**Ansjie Miller, Center for Environmental Health:** Given increasing interest in data provided by IRIS assessments how will the EPA ensure that this data is completed in a timely manner to enable governments, businesses, the public interest community and consumers to make health-protective decisions?

**Kacee:** Thanks. What is your affiliation?

**Ansjie:** Center for Environmental Health

**Kacee:** Thanks.

**Ansjie:** How can those of us on the webinar who cannot regularly come to DC stay engaged in this process?

**Ansjie:** How to engage more stakeholders in IRIS? Identify communities that would be vulnerable to exposures to the chemical undergoing assessment and outreach to organizations that represent and organize within those communities. Webinars and meetings in regional offices would be helpful. But we shouldn't have more meetings that would slow the process.

**Ansjie:** Also, I would recommend changing the comments and feedback process in seeding questions and comments from the webinars. By the time our questions come up, the conversation has moved on and I would have asked my question or given feedback differently.

**Craig Selover, Masco Corporation:** given the concern about endless studies to generate more information, are there any rules or guidance regarding things like Mode of Action that should be applied to determine what studies qualify to be included in the IRIS database?

**Kacee:** Hi Craig. Your question is in the queue. What is your affiliation?

**Craig:** Kacee - FDA asked essentially the same question I had. In the interest of time, I'm fine with skipping my question.

**Kacee:** Okay - thanks Craig.

**Angela Curry, Texas Commission on Environmental Equality:** TCEQ has historically considered IRIS assessments as the gold standard, and since any differences in scientific judgment between USEPA and TCEQ were generally relatively small (e.g., choice of a UF value) toxicity factors were used as derived by IRIS. While the TCEQ has serious concerns about the scientific defensibility and objectiveness of some recent IRIS assessments (e.g., dioxin, arsenic, formaldehyde, CrVI) such that the agency no longer has the highest confidence in IRIS values, the TCEQ's confidence in the IRIS program can be restored if shortcomings of the IRIS program are substantively addressed and the scientific merit of comments submitted (early in the process) is rigorously evaluated and truly addressed. Joseph Haney TCEQ

**Kacee:** Thanks Angela. Your comment is in the queue.

**Angela:** Currently, it appears that the USEPA timeline is insufficient: (1) for the public to be able to provide fully detailed comments on the many shortcomings of the draft assessments (which would be better earlier in the process); (2) for USEPA to seriously and meaningfully evaluate the scientific merit of public comments (e.g., the assessment has already been completed); (3) for USEPA to conduct the additional analyses required to fully respond to public comments and appropriately revise the draft assessment based on the scientific merit of comments; and (4) for USEPA to conduct the fully credible, balanced, and transparent assessment the public deserves where the effects of the significant uncertainties associated with certain key decisions and procedures are fully examined qualitatively and quantitatively. Additionally, the SAB should be balanced and where different opinions exist between members on a particular question, the expertise of those members should be considered.

**Kacee:** Thanks Angela.

**Angela:** From Roberta Grant at TCEQ: How many IRIS toxicologists/chemical risk assessors are in the program and how many work on each chemical (i.e., do you have adequate staff)?

**Sonya Lunder, Environmental Working Group:** EWG is concerned about the definition of conflict of interest for IRIS expert review panels. As many remember, Deborah Rice was deemed to have an appearance of a lack of impartiality for Deca PBDE, meanwhile dozens of scientists with strong ties to industry are allowed to advise IRIS assessments. We would like to see EPA's conflict of interest policy clarified to support the engagement of public servants and limit the role of consultants with financial ties to chemical manufacturers who might be affected by IRIS decisions. How can EPA clarify conflict of interest for expert reviewers?

**Kacee:** Thanks Sonya. Your comment is in the list.

**Tracey Woodruff, University of California, San Francisco:** We applaud EPA for conducting this review and input into the IRIS program. IRIS is a leader in risk assessments, recognized around the world. It is extremely timely to be upgrading IRIS, as our understanding of science and science evaluation has greatly expanded since the implementation of IRIS.

**Kacee:** Thanks Tracey. Your comment is in the queue.

**Tracey:** We agree with the move toward systematic reviews as a framework for IRIS risk assessments. As Dr. Coglianò stated, IRIS can build off the rich experiences of clinical medicine in their efforts to implement systematic reviews. We would like to note that this experience in clinical sciences is encapsulated in GRADE (based on Cochrane reviews). However, when adopting these approaches, the difference in evidence streams in clinical and environmental health sciences must be accounted for.

**Tracey:** To bridge this gap of decision context and evidence streams, methods used in the clinical sciences need to be adapted for use in IRIS. To this end, in May 2011, in collaboration with 22 clinical and environmental health scientists we published such a methodology – called the Navigation Guide in Health Affairs. Importantly, it requires that decisions on how the data will be found, evaluated and synthesized be decided a priori, which can be reviewed by key stakeholders. This is the opportunity to get stakeholder input and thus expedite the process.

**Tracey:** Due to differences in the regulation of exogenous chemicals used as pharmaceuticals and chemicals used in commerce, the burden of proof of safety is required for pharmaceuticals before population exposure occurs whereas there is no such comparable regulatory burden for most of the chemicals in commerce today. In addition, clinical methods of systematic review rely on experimental human studies which are virtually precluded from environmental health sciences and environmental health science relies on non-human evidence for decision-making for timely decision-making.

**Kacee:** Thanks Tracey - I may split your comments up a bit to make them more readable. Is that okay with you?

**Tracey:** The Navigation Guide allows for evaluating risk of bias of studies, which includes considering financial interest of the party that conducts or sponsors a study. It has been clearly shown in the pharmaceutical and tobacco literature that funding source biases outcomes. This does not mean studies should not be included – all studies should be included, but evaluated based on potential for being biased. We are currently in the process of demonstrating proof of concept of the method and encourage EPA to test this method as they work to improve

IRIS.

**Kacee:** Tracey - what is "The Navigation Guide" -- do I need to explain when I make your comment?

**Tracey:** I think it could be read at once, but I'm not there

**Kacee:** Okay - I will do it all at once. Thanks.

**Tracey:** Per your question - the Navigation Guide is a systematic review approach based on GRADE that integrates evidence-based medicine with environmental health evaluation. You can insert that after the name navigation guide

**Tracey:** Do you want me to resend my comment with that information in there?

**Kacee:** No, that's okay. I've got it.

**Tracey:** Thanks - will our comments be given soon?

**Kacee:** Hi Tracey - you have about 6 people in front of you. We've had a lot of questions and comments come in on the webinar.

**Tracey:** Ok - thank you. Just my perception on the phone, but it seems like we haven't had as much time for webinar comments.

**Kacee:** Sorry, I know it's not the same as being in the room! We are learning as we go, and hopefully we'll figure out a way to make things a bit more "equal"... But we are alternating between the room and webinar.

**Tracey:** Also, if you want to converse by email, that would be helpful...but either way. If you want to call me and check it out - here is my number 415 624 9959 - I am going to get something to eat too! Thanks.

**Tracey:** Thank you Kacee for giving us a little more time.

**Kacee:** You're welcome! For some reason, the panelists are reacting more to the people at the microphone than to me reading a question/comment. This is something we will work on for future meetings. As a webinar participant, if you have any suggestions, I would appreciate them!

**Tracey:** We can't hear the speaker BTW

**Kacee:** They are fixing the floor mic. It died.

**Tracey:** Thanks!

**Tracey:** Hi, it would be great if you could read more comments from online before letting in the room commenters from going twice. Sorry to be so persistent, but it is a little hard to see where we are in terms of getting our comments heard.

**Tracey:** I am trying to figure out what is a good process. I want to hear from the panel, but sometimes there is too much comment from the panel. Maybe you could ask people when they send their comments to identify a panel member they would like to respond. Like David did. But maybe tell commenters (like me) to also include a question. I should know this, but I forget sometimes!

**Tracey:** One idea is to time how much each speaker is getting, and equalize time in room versus online as you go along (I suspect the online comments are shorter). Also, it would be helpful to limit the panel members' comments, since it limits the ability of others to speak. Thank you!!

**Tracey:** Hi, one thing helpful would be that speakers on the floor only get one chance to speak - given so many people waiting virtually. Thanks!

**Tracey:** Do you think you could read through the rest of the comments in the cue before the end without reply?

**Stephenie Hendricks, Consultant at Coming Clean:** Excellent points from Jen Sass, I agree!

**Stephenie:** How about this one: During the Bush administration there was a gag order put on EPA scientists to talk to the public. Is this still in effect and how free are EPA scientists to voice their concerns about industry influence on environmental health protections regulations such as IRIS? Also, will long term neurotoxic health impacts be included and expanded in IRIS evaluations?

**Desmond Bannon, DOD:** IRIS values ultimately rest on toxicity studies modified by default factors. Weak studies with blind application of default factors results in promulgated values that have low credibility with many stakeholders. How can EPA avoid this and raise credibility in the IRIS values?

**Kacee:** Thanks Desmond. Your question is in the queue. What is your affiliation?

**Desmond:** Desmond Bannon, DOD.

**Kacee:** Thanks - got it.

**Maureen Swanson, Learning Disabilities Association of America:** Thank you for including health organizations in this meeting, as it is critical that IRIS assessments are completed in a much timelier manner. LDAA urges EPA to adopt stopping rules and other measures that will end the years - sometimes decades - long process of assessing chemical risks. It's inexcusable that vulnerable populations such as the developing fetus and children continue to be exposed to chemicals that can cause birth defects or cancer, such as TCE, while the chemical industry demands yet another study or review.

**Kacee:** Thanks Maureen. Your question/comment is in the queue.

**Divinia Ries, Michigan DEQ:** Support transparency and probably solving trust issues by opening meeting to interested parties and publishing all documents including meeting minutes and documents submitted by industry and other stakeholders.

**Kacee:** Divinia- your comment is in the list. Thanks!

**Divinia:** Increase assessment throughputs by conducting preliminary reviews for all chemicals with no IRIS assessment record or 2-3 year old assessment files. Then IRIS should develop and publish interim values (e.g. PPRTVs) for regulatory use. This will alleviate the timeliness issue and will encourage stakeholders to actively participate in contributing data to the draft assessment.

**Amy D. Kyle, University of California Berkeley School of Public Health:** Please ask the facilitator to use the first and LAST name of the people being referred to.

**Kacee:** Will do. Thanks.

**Amy:** Thanks. It is hard to follow on the webcast.

**Amy:** Topic: Systematic review and consideration of data gaps. Question and comment: Systematic review is useful for organizing the data that are available. However, it has little to say about the implications of limited or incomplete or conflicting evidence. Yet, consideration of what is missing from an evidence base is as important as consideration of what is present. How is EPA planning to better address the limitations of the information available, both during the synthesis and also in developing toxicity values.

**Kacee:** Amy - your comment/question is in the queue. What is your affiliation?

**Amy:** Topic: Metrics generated from IRIS. Question and comment: IRIS has largely focused on producing metrics that are useful for "old school" risk assessments such as those developed for regulation of major chemicals. Is EPA considering any more nimble process to generate metrics that could be used to COMPARE chemicals such as through alternatives assessment. These are needed in a variety of contexts including but not limited to EPA's "design for environment" program, which currently has to generate conclusions based partly on questionable metrics.

**Amy:** I don't see how to submit the response to the poll. There is no "submit" button or anything like that

**Maureen:** Once you pick a button it is recorded until I close the poll. Thanks for your input =)

**Frank Speizer, Harvard University:** Underlying much of the problem in the IRIS program is that it sorely underfunded. There needs to be a development of staff personnel who are funded appropriately to do proper risk assessment of existing peer review literature. By limiting the database to peer review literature much of the conflict of interest (COI) and "lack of trust" may be handled by journal editors who have become more concerned about assessing these COI. Too often the input from the "interested stakeholders" is not peer reviewed, and often is biased. If we were to require that the data base be peer reviewed it should help industry provide the incentives to their own scientists to engage in the scientific process, rather than appearing as simply critics of

efforts made by the constituted scientific vetted panels EPA employs to review the staffs work. I do not believe that expanding the committee beyond their current representative sizes will help in shortening the review process.

**Kacee:** Your question has been logged and is in the queue. Thanks!

**Eileen Murphy, Rutgers University:** I am concerned about integrating the opportunity for public and stakeholder comment with the peer review process. They are separate issues. Peer review is a rigorous technical review of the IRIS document, whereas stakeholder/public review can range from technical comments to policy questions. It is inappropriate for the external peer reviewers of IRIS documents to address stakeholder/public comments during their peer review. I would be interested in hearing the rationale for combining these two types of reviews.

**Kacee:** Hi Eileen - your comment is in the queue.

**Penny Fenner-Crisp, Consultant & EPA retiree:** Upwards of 40% of the substances currently on IRIS are there by virtue of their introduction into the environment as pesticides registered by OPP. Most of the IRIS values were generated in the 1980's (mostly by me, Mike Dourson and Reto Engler before the RfD Committee was established). The mandates of FQPA have resulted in a reevaluation of these chemicals either in the re-registration or registration renewal programs. These reassessments now render many of the IRIS values out of date. The one-off links to OPP's RED/IREDS, etc was somewhat useful for a time, but, since then, even some of OPP's re-assessments have undergone further changes. In order to improve the credibility of the IRIS database as a whole, at a minimum, the outdated IRIS summaries for these chemicals should be removed from the database. Other options include replacing the IRIS values with OPP's or removing the chemicals entirely from the IRIS database, challenging OPP to create its own.

**Kacee:** Penny - your question/comment is in the queue.

**Jacqueline Patterson, Toxicology Excellence for Risk Assessment:** My name is Jacqueline Patterson and I manage a non-profit independent peer review program for TERA. I want to thank EPA for today's session and the opportunity to hear directly from EPA and from the wide variety of stakeholders on important issues and developments with IRIS. I am very pleased that EPA is committed to improving IRIS peer review. High-quality, independent peer review is essential to insure IRIS assessments are of excellent quality and are credible. In particular I encourage EPA to make sure that the peer review panels include experts with sufficient experience in risk assessment. The IRIS assessments often involve complex and sometimes conflicting data; multiple experts from the key disciplines are needed who can discuss and interpret the data in a risk assessment context. Peer review panels should be constructed so that robust discussions are possible and controversial issues are fully addressed by scientists with different opinions and perspectives.

**Kacee:** Thanks. Your comment is in the queue.

**Jacqueline:** It sounds like you won't be able to take anymore webinar comments. There must be many comments not yet read - I've been in the queue since before 3:30. Will these extra comments be shared with EPA and others?

**Kacee:** Hi Jacqueline - I'm very sorry -- about a dozen questions weren't answered. We had a lot in the queue early on (during the panel and at the beginning of the open forum). We are keeping a record of all of the comments and questions and we will provide a "virtual" comment box on the IRIS website. Please be assured, the IRIS leadership will see your comment!

**Johanna Congleton, Environmental Working Group:** Does the EPA IRIS program plan on increasing the role of biomonitoring data, as recommended by the National Academies of Science in "Science and Decisions" (2009)? If so, are there specific strategies under discussion to do so?

**Kacee:** Johanna - your question is in the queue. Thanks!

**Nancy Buermeyer, Breast Cancer Fund:** Thank you for hosting this meeting, particularly allowing those of us outside of DC to participate, and we look forward to continuing to engage in this dialogue with the IRIS program. It is hard to express the frustration created by the endless delays on finishing these assessments. 20 years to assess chemicals such as formaldehyde, styrene and dioxin is unacceptable. People are getting sick now and the agency cannot allow industry to delay these assessments for decades. "Transparency" cannot be allowed to be a code word for endless delays. There will always be uncertainty in the science, and the IRIS program cannot allow the industry to use that uncertainty to hamstring the process. Uncertainty is not an excuse for inaction. The EPA's mission is to protect the American public. We are your clients, not the chemical industry, and we look forward to working with you to improve and streamline this process.

**Kacee:** Nancy - your question/comment is in the queue. Thanks!

**Nancy:** Thanks, Kacee! Can I add another short one or do I only get one bite at the apple?

**Kacee:** You can add another.

**Nancy:** Can I suggest you do a couple of web comments for every in the room comment? Otherwise we'll never get through the shorter and more concise statements from those of us on the web.

**Kacee:** I will speak with the room moderator.

**Nancy:** Thanks - Public engagement would be greatly enhanced by holding these types of meetings outside of Washington, DC. While we appreciate the ability to participate via the web, folks in the room can clearly talk faster than we can type.

**Craig McCormack, Washington Department of Ecology:** Based on resources, not all "stakeholders" can engage in this process in the same way and at the same level of technical detail. How do you, EPA and NTP, intend to level the playing field so that all stakeholders can be heard? This is not just an issue that can be responded to with systematic review process.

**Craig:** Weight of Evidence approaches implies scientific judgments to be made during scientific evaluations, reconciling prudent public health and environmental policies with ACC's reproducibility criterion may not be able to be done or done in a timely manner. Please comment-Jim

**Craig:** How does EPA intend to prioritize chemicals that need IRIS assessments?

**Patrice Sutton, UCSF Program on Reproductive Health and the Environment:** I am commenting on the issues of stakeholder input, trust and timeliness of IRIS assessments being discussed. First, I want to underscore the import of Dr. Denison's comment on timeliness. There are unequal benefits and risks to delaying these assessments, with the health burden falling on the exposed public. This results in critical losses in terms of timely prevention. We strongly recommend that decision-making needs to be done based on the available evidence, with updates as needed. We do not need perfect data to make a decision. We only need data that are sufficient to the decision at hand.

**Patrice:** This comment has another part as follows, I could not fit it in the box. We also suggest that EPA's IRIS public engagement process acknowledge that there is a structural difference between the interests of the regulated community and the public who will be exposed to the chemical. The regulated community is responsible to their shareholders. In contrast, the public has a wide range of values and preferences that can include but are not limited to health, jobs, cost, etc. In the clinical sciences, systematic review methodologies that are used for evidence based decision-making separate these competing interests out by distinguishing the "strength of the evidence" from the "strength of the recommendation." This means that the strength of the evidence produced by a systematic review is just the data – the competing "values and preferences" are addressed in the recommendation or decision at hand. We would propose that EPA bring this awareness and experience from the clinical sciences into the IRIS process to ensure

**Patrice:** that if decisions are delayed it is transparent that it is competing values and preferences, not science, that

is causing the delay.

**Patrice:** Forgot to mention my affiliation is UCSF Program on Reproductive Health and the Environment.

**Patrice:** It would be great in terms of public engagement to level the playing field so webinar people can speak and not be limited to the size of these boxes - thank you!

**Kacee:** Patrice - thanks, your question is in the queue. Sorry about the text limit in the comment box!

**Katie Huffling, Alliance of Nurses for Healthy Environments:** Nurses, such as myself, and other members of the public health community rely on IRIS assessments in our health care practices. When an assessment is delayed, it translates into increased incidence of illness, even death.

**Jerry Poje, Society for Occupational and Environmental Health:** Even the impressive 450 participants on today's forum and webinar audience is but a small portion of likely public interest, government and industry participants with IRIS products. What's the likelihood of several smaller locality and state model public engagement projects over the next two years? To hone a more effective public engagement model will require many different attempts at public trust building with locally defined chemical hazards and exposures.

**Annie Jarabek, NCEA:** John Vandenberg mentioned the ISA process, which relies on CASAC -- the Clean Air Science Advisory Committee. CASAC is a standing committee and as such becomes more familiar with the operating procedures of the Agency. In contrast, case-by-case peer reviews are not consistent with respect to their understanding of Agency constraints and operating procedures. Is this another lesson to be learned for IRIS from the ISA process?

**Steven DeSantis, NYSDEC:** The EPA's NESHAP program uses IRIS in its Risk and Technology Review Program. Does IRIS staff plan to establish acceptable short-term health effect concentration values., 1-hour or 8 -hour. In previous NESHAP assessments EPA used accidental release concentration values (AEGL) for short-term assessments and these values are not appropriate.

**Kacee:** Hi Steven - your question/comment is in the queue. NYSDEC is New York State Department of Environmental?

**Steven:** Conservation

**Kacee:** Thanks!

**Paula Johnson, University of California at San Francisco – Program on Reproductive Health and the Environment:** The issue of “scoring” in systematic reviews has come up several times during this discussion. This is an example of an area where consulting with experts in systematic reviews (such as Cochrane Collaborative or GRADE) would be very useful. Quality scoring, while originally popular for systematic reviews, has evolved out of practice, as empirical evidence found that it was not a fully systematic approach. The GRADE approach is favored in the clinical science arena and can be usefully adopted in translating evidence in the environmental health sciences where animal experimental data and human observational studies are reviewed. Additionally, GRADE is a transparent approach that where judgments are documented during the review process.

**Amanda McKay, Floyd Snyder, Inc.:** was late to the webinar--will it be available online for later viewing?

**Kacee:** Hi Amanda - the presentations will be available on the website a few days after the meeting.  
[www.epa.gov/iris/publicmeeting.htm](http://www.epa.gov/iris/publicmeeting.htm)

**Amanda:** OK thanks, a video or just PowerPoints? Appreciate your response.

**Pertti Hakkinen, NIH NLM:** The online "How would you like IRIS to engage the public more?" poll only allows one choice! There should be multiple choices!

**Kacee:** Please feel free to vote twice (if the system lets you) if you want to pick more than one option.

**Pertti:** Thanks. Actually, I'm not seeing a "submit" button on my screen. I'm not sure my vote(s) is getting counted.

**Kacee:** We will also have a virtual comment box on our website after the meeting, and you can post comments and suggestions there. Thanks!

**Kate Sande, Minnesota Department of Health:** I don't have a comment about the panelists. I just wanted to send a note stating that I'm not submitting a vote on the question that popped up on our screen because it doesn't allow for more than one selection...I would have selected more workshops/webinars early on and mailing list updates. Thanks, Kate Sande, Minnesota Department of Health

**Maureen:** Thanks, it looks like the poll only allows for one vote, so thank you for submitting your follow-up comment.

**Mike Schade, CHEJ:** A classic example of how a chemical assessment has been delayed for many, many years, has been dioxin. EPA's dioxin assessment was reviewed by multiple SAB peer review panels, and time after time, industry only asked for more delays and more reviews, meanwhile vulnerable populations continued to be exposed to potentially harmful levels of dioxin. We were very pleased that EPA, after nearly 30 years, finalized its IRIS noncancer assessment for dioxin earlier this year. However at the same time, EPA has still not finished the dioxin cancer assessment. It has been over one year since the SAB completed its dioxin review, and nine months since EPA finalized the noncancer assessment – what is the status and timeframe for completing EPA's dioxin cancer assessment? How much longer will we have to wait? We've been waiting for nearly 30 years already. Thank you.

**Mike:** How come my question wasn't answered? I posted it at 4:12pm

**Kacee:** I'm sorry -- there are about a dozen questions that were not answered. Many, many people posted during the panel presentations and in the beginning of the open forum. I have captured all of the comments and questions on the webinar. Additionally, we will have a virtual comment box on the IRIS website so you can post a comment if you weren't able to today.

**Mike:** OK, thanks.

**Steve Risotto, ACC:** Question for Ken Olden - In discussions with the NAS committee on perchloroethylene, NCEA staff indicated that they feel that their objective is to find the health end point that generates the lowest (most conservative) risk value regardless of whether that end point is relevant to human health assessment. In your mind, is that the appropriate role for the IRIS program?

**Steve:** Why wasn't my question asked?